Testimony of
Susan F. Wood, PhD
May 17, 2006

Subcommittee on Criminal Justice, Drug Policy, and Human Resources
Committee on Government Reform
US House of Representatives

Chairman Souder and Members of the Subcommittee:

My name is Susan F. Wood, PhD and for the last 15 years I have worked in women's health policy within the Federal Government. In each of my positions I have advocated for the promotion of women's health, through increased research, services and prevention. From November of 2000 through August of 2005, I was the Assistant Commissioner for Women's Health and Director of the Office of Women's Health at the US Food and Drug Administration. Prior to that, I was Director of Policy and Program Development at the Department of Health and Human Services Office on Women's Health. I began my work in women's health in 1990 as Congressional staff to the bipartisan Congressional Caucus for Women's Issues, initially as a fellow in the program sponsored by the American Association for the Advancement of Science, and then as professional staff to the Caucus. My scientific training is as a PhD in Biology and my research focused on basic cell biology and biochemistry carried out at Boston University and at Johns Hopkins University School of Medicine.

Over the last 15 years, I am proud to have been part of the advances we have made in women's health: expanded research at the NIH in areas such as breast and ovarian cancer, osteoporosis, heart disease, HIV/AIDS and menopause; more inclusion of women in clinical research studies funded by NIH and regulated by FDA; increased screening of women for cancer and for sexually transmitted diseases that lead to infertility; better quality mammography; coverage for preventive screenings by Medicare; and improved prevention and services for victims of domestic violence.

While I was at the FDA, the Office of Women's Health supported groundbreaking research, including research on medications taken during pregnancy to help find out what the proper doses of different medications should be during the different stages of pregnancy. We also funded important health outreach programs in areas such as safe medication use, diabetes, and menopause and hormone therapy. The Office also worked to implement and track the inclusion of women in clinical studies reviewed by FDA and to ensure the analysis of the data for important sex differences in safety and efficacy.
These advances and more were made through the concerted efforts of Members of Congress, the various agencies of the Department of Health and Human Services, the research and clinical communities, and women's health advocates around the country. One of the core principles that led to progress was and remains: ensure that we move forward based on the best available scientific and medical evidence. And when that evidence is lacking: go out and do the studies necessary to get it.

My commitment to women's health is founded on these scientific principles, knowing that this is the best way to expand our knowledge and improve the health of women and men both here in the US and abroad.

My commitment to women's health, particularly to drug safety, is also founded in personal experience. I lost my much loved sister to cancer at age 34, caused directly by a drug given to our mother while she was pregnant, the drug diethylstilbestrol – known as DES. I can assure you my commitment to drug safety for women is deeply felt and always at the forefront of my mind.

I appreciate your invitation to testify before this subcommittee on the issue of mifepristone and whether or not FDA has held this drug to the best standard of review on safety and efficacy.

I was working in the DHHS Office on Women's Health at the time of the mifepristone review, and therefore have no direct knowledge of the evaluation and review that was happening at the FDA. That is exactly as it should be. The FDA was working independently, reaching its conclusions and decisions based on its usual processes and evaluation of the data. In fact, there was curiosity among many of us at the Department level about the subject, but we were given clear instruction by senior management at the Department that we were not to inquire, even informally, of our women's health colleagues at FDA about the status of the mifepristone application. This was to ensure that there was not even a perception of Departmental influence on this highly visible application. Upon my arrival at FDA in the fall of 2000, this independence of decision-making was confirmed to me by the professional staff that was directly involved in the review. The evidence presented to FDA and the subsequent experience with the marketed product in the US tells us that this is a safe and effective method for early termination of pregnancy.

The recent deaths due to Clostridium sordellii in women who had had a medical abortion are truly tragic. I offer my sincere condolences to Mr. Patterson, his family, and the families of all of the women. These rare deaths due to this bacterial infection have put us on notice that health professionals and women need to be aware of this potential risk.

More importantly, the close surveillance of adverse events associated with the use of mifepristone have alerted us that this bacterial infection is present and has caused the deaths of other women who have given birth or had a miscarriage – more in fact than the number of women who underwent a medical abortion. This pattern of infections and death after pregnancy is indeed disturbing, and tells us once again that we need to do more to ensure safe pregnancy and safe motherhood. This is not limited to women who have been exposed to mifepristone, and to focus solely on women who have had a medical abortion is to miss the real threat to the health of women. Our surveillance systems for maternal mortality and morbidity have been limited over the years due to limited funding and lower priority. These systems need to be improved and expanded to capture not only the impacts of Clostridium, but also so that we can understand and prevent the other risks that women face with pregnancy. With mifepristone we can be confident that we have identified all or most of the adverse events and deaths. We cannot say the same for infections and deaths caused by C. sordellii in women who have given birth or had a miscarriage.

I applaud the CDC, the FDA and the NIH for holding the scientific meeting May 11, 2006 on Clostridium infections, to begin the process of examining the data that we currently have on the nature of these infections, potential strategies for prevention, early detection and effective treatment, and the research agenda that needs to be undertaken to answer the critical questions that exist. Although I did not attend, I understand that the meeting participants presented current information and discussed the future needs to address this emerging infection.

Questions have been raised about whether mifepristone is involved through suppression of the immune system. This is a question to be studied, but at this point does not seem to be a compelling mechanism. If the immune system were suppressed, we would also expect to see a rise in other more common infections. Also, although progesterone suppresses the immune system normally in pregnancy, mifepristone is an anti-progestin and might be expected to counter this normal suppression of the immune system. We would also expect to have seen this infection in places using the higher doses of mifepristone, but, in fact, use in the US is of a much lower dose (usually one-third) than that commonly used in Europe. Similarly we would expect to see this infection in cancer patients who have used mifepristone over longer periods of time. This pattern thus far has not emerged.

Experts at CDC, FDA and NIH reviewed the current information and appeared to recognize that the infections and deaths due to C. sordellii are not due to a simple drug effect. Rather this is a complex situation that involves multiple factors that are linked to pregnancy. Getting to the bottom of what puts women at risk for this infection, and what can be done to prevent and treat it, is of the highest importance.

The experts at the meeting last week identified several clear areas of research that are needed, including improved surveillance of infection in women who have given birth or had a miscarriage, improved diagnosis, the role of antibiotics, the possible development of an antitoxin or other therapies, and further research on the nature of the Clostridium bacteria. We need to know what makes this strain toxic: is it interactions with the environment; why are these deaths thus far localized in the west; and what in pregnancy or in the woman's body leads to production of the toxin? I strongly urge the Subcommittee to support this research and surveillance agenda to address this threat to women's health. By doing so, we can improve the health outcome of all pregnant women and also help ensure improved maternal outcomes. Please do not allow politics to trump science once again when the health of women is at stake.